

Form PTO-1449

**INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION**  
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Docket Number (Optional) A-1789dlv

Application Number 10/716739

Applicant Pandian et al.

Filing Date herewith

Group Art Unit 1641

**U. S. PATENT DOCUMENTS**

| EXAMINER<br>INITIAL | DOCUMENT NUMBER | DATE     | NAME            | CLASS | SUBCLASS | RULING DATE<br>IF APPROPRIATE |
|---------------------|-----------------|----------|-----------------|-------|----------|-------------------------------|
| GC                  | 4,946,958       | 8/1990   | Campbell et al. |       |          |                               |
| GC                  | 5,356,817       | 10/2002  | Cole et al.     |       |          |                               |
| GC                  | 5,506,150       | 4/09/96  | Canick et al.   |       |          |                               |
| GC                  | 5,660,990       | 08/1997  | Rao et al.      |       |          |                               |
| GC                  | 6,127,186       | 10/03/00 | Pandian         |       |          |                               |
| GC                  | 6,352,862       | 03/2002  | Davis et al.    |       |          |                               |

**FOREIGN PATENT DOCUMENTS**

|    | DOCUMENT NUMBER | DATE       | COUNTRY | CLASS | SUBCLASS | TRANSLATION |    |
|----|-----------------|------------|---------|-------|----------|-------------|----|
|    |                 |            |         |       |          | YES         | NO |
| GC | 98/10282        | 3/12/1998  | WO      |       |          |             | No |
| GC | 99/41584        | 8/19/1999  | WO      |       |          |             | No |
| GC | 99/56132        | 11/04/1999 | WO      |       |          |             | No |
| GC | 00/42428        | 7/20/2000  | WO      |       |          |             | No |
| GC | 00/70094        | 11/23/2000 | WO      |       |          |             | No |

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

|    |   |
|----|---|
| GC | Bahado-Singh R et al., "A high-sensitivity alternative to 'routine' genetic amniocentesis: multiple urinary analytes, nuchal thickness, and age." Am J Obstet Gynecol 1999 Jan;180(1 Pt 1): 169-73.   |
| GC | Cole LA et al., "Urinary screening tests for fetal Down syndrome: I. Fresh $\beta$ -core fragment." Prenat Diagn. 1999 Apr, 19(4): 340-50.  |
| GC | Bahado-Singh RO et al., "New triple screen test for Down syndrome: combined urine analytes and serum AFP." J Matern Fetal Med. 1998 May-June;7(3):111-4.  |
| GC | Kellner LH et al., "Levels of urinary beta-core fragment, total oestriol, and the ratio of the two in second-trimester screening for Down syndrome." Prenat Diagn. 1997 Dec;17(12):1135-41  |
| GC | Cole La et al., "Combining beta-core fragment and total oestriol measurements to test for Down syndrome ..." Prenat Diagn. 1997 Dec;17(12):1125-33.   |
| GC | Cuckle HS et al., "Urinary multiple marker screening for Down's syndrome." Prenat Diagn. 1995 Aug;15(8):745-51.   |
| GC | Bahado-Singh RO et al., "Comparison of urinary hyperglycosylated human chorionic gonadotropin concentration with the serum triple screen for Down syndrome detection in high-risk pregnancies." Am J Obstet Gynecol. 2000 Nov;183(5):1114-8 |
| GC | Cole LA et al., "Urinary screening tests for fetal Down syndrome: II. Hyperglycosylated hCG." Prenat Diagn. 1999 Apr; 19(4):351-9   |
| GC | Cole LA et al., "Hyperglycosylated hCG, a potential alternative to hCG in Down syndrome screening." Prenat Diagn. 1998 Sep; 18(9):926-33.   |
| GC | Hsu JJ et al., "Urine free beta-hCG and total estriol for Down syndrome screening during the second trimester in an Asian population." Obstet Gynecol 1999 Jul;94(1):107-11.  |

EXAMINER

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Form PTO-1449

Docket Number (Optional) A-1789div

Application Number 10/ 716737

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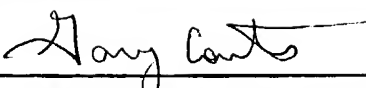
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|   |                 |      |         |       |          | YES         | NO |
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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

|    |  |
|----|--|
| gc | Spencer K et al., "First-trimester urine free beta hCG, beta core, and total oestriol in pregnancies affected by Down's syndrome: implications for first-trimester screening with nuchal translucency and serum free beta hCG." Prenat Diagn 1997 Jun;17(6):525-38.  |
| gc | Isozaki T et al., "Screening for Down syndrome pregnancy using $\beta$ -core fragment: prospective study." Prenat Diagn 1997 May;17(5):407-13.   |
| gc | Spencer K et al., "Urine free beta hCG and beta core in pregnancies affected by Down's syndrome." Prenat Diagn 1996 Jul;16(7):605-13   |
| gc | Krichevsky A et al., "The development of a panel of monoclonal antibodies to human luteinizing hormone and its application to immunological mapping and two-site assays." Endocrine 1994, 2, 551-520   |
| gc | O'Conner JF et al., Differential Urinary Gonadotrophin Profiles in Early Pregnancy and Early Pregnancy Loss." Prenat Diagn 18: 1232-1240 (1998)  |
| gc | Unknown "Serum Hyperglycosylated hCG: a Potential Screening Test for Fetal Down Syndrome." Prenat. Diagn. 19:488-490 (1999)  |
| gc | Cole LA et al., "Hyperglycosylated Human Chorionic Gonadotropin (Invasive Trophoblast Antigen) Immunoassay: A New Basis for Gestational Down Syndrome Screening." Clinical Chemistry 45:12-2109-2119. (1999).  |
| gc | Abushoufa RA et al, "The development of a sialic acid specific lectin-immunoassay for the measurement of human chorionic gonadotrophin glycoforms in serum and its application in normal and Down's syndrome pregnancies." Clinical Endocrinology (2000) 52, 499-508.                                      |
| gc | Birken S. et al., "Development and Characterization of Antibodies to a Nicked and Hyperglycosylated Form of hCG from a Choriocarcinoma Patient." Endocrine, 10:(2) 137-144 April 1999.   |
| gc | Krichevsky A. et al., "Development, Characterization, and Application of Monoclonal Antibodies to the Native and Synthetic $\beta$ COOH-Terminal Portion of Human Chorionic Gonadotropin (hCG) That Distinguishes between the Native and Desialylated Forms of hCG" Endocrinology 1994 Mar;134(3):1139-45. |
| gc | Krichevsky A. et al. "Development and Characterization of a New, Highly Specific Antibody to the Human Chorionic Gonadotropin- $\beta$ Fragment." Endocrinology 1991 Mar;128(3):1255-64.   |
| gc | "Utility of Commonly Used Commercial Human Chorionic Gonadotropin Immunoassays in the Diagnosis and Management of Trophoblastic Diseases" by Cole et al.; Clinical Chemistry, Feb. 2001, vol. 47, no. 2, pages 308-315   |
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